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EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 08/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/394,745	FISHER ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-10 and 12-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10 and 12-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The present Office Action is responsive to the Amendment received on June 7, 2006.

Preliminary Remark

Claims 1-7 and 11 are canceled.

Claims 8-10 and 12-27 are pending and are under prosecution.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of claims 8-10 and 12-27 under 35 U.S.C. 101 because the claimed invention lacks patentable utility, made in the Office Action mailed on March 8, 2006 is maintained for the reasons of record.

Applicants' arguments presented in the Amendment received on June 7, 2006 have been fully considered but they are not found persuasive for the reasons set forth in the, "Response to Arguments," section.

The Rejection:

Definitions: [from REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from http://www.uspto.gov/web/menu/utility.pdf, also available on MPEP 2107.01(I)(B)):

> "Credible Utility" - Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered

by the applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the *specific* and *substantial* tests (see below).

"Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention. For example, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be *specific* in the absence of a disclosure of a specific DNA target. Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed.

"Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a *specific* or *substantial* utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. § 101. This

> analysis should, or course, be tempered by consideration of the context and nature of the invention. For example, it a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial *asserted* utility would be considered to be met.
>
> "Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

[See also the MPEP at §§ 2107 - 2107.02].

The claimed combination of nucleic acids comprised on a substrate or as a microarray is not supported by a substantial utility because the disclosed uses of the nucleic acids are generally applicable to any nucleic acid. The specification states that the nucleic acid of the microarray are ESTs (expressed sequence tags) which have been derived from LIB189 cDNA library, which was prepared from leaf tissue harvested at anthesis from field grown *Zea mays* genotype RX601 plants (pp. 33-39; see also pp. 92, lines 8-14), and thus ***useful for studying the genes that are agronomically significant*** (pp. 33, 1st paragraph and throughout), expression studies (pp. 43), ***detection of polymorphisms*** (pp. 45-49), and for ***numerous other generic genetic engineering usages***.

There is no evidence that LIB189 is a subtractive cDNA library, wherein nucleic acid molecules from maize tissue other than leaf tissues, from developmental stages other than anthesis, and/or from *Zea mays* plants other than genotype RX601 is subtracted (removed) from the library.

In addition, there is no evidence that any of the nucleic acids comprised in the claimed microarray are expressed only at the time of "anthesis," only in leaf tissue, or only in *Zea mays* plant having the RX601 genotype.

Hence, Applicants' asserted utilities are considered to be non substantial because no substantial utility has been established for the claimed subject matter. For example, a microarray comprising ESTs could be used as a research tool and not substantial in it usage for a particular detection. Unless the array, or the probes fixed on the array (i.e., nucleic acids), are specific for a certain disease, condition, or certain agronomically significant traits, the nucleic acids is only useful for conducting further research to find a substantial utility. The need for such research clearly indicates that the nucleic acid is not disclosed as to a currently available or substantial utility. The research contemplated by applicant(s) to utilize the nucleic acids to conduct find agronomically advantageous traits, such as their biological activities, does not constitute a specific and substantial utility. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acids such that another non-asserted utility would be well established for the compounds.

The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 USPQ 689 (1966), wherein the court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. 101, which requires that an invention must have either an **immediately apparent** or fully disclosed "real world" utility (emphasis added). The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...[u]nless and until a process is refined and developed to this point-where specific

> benefit exists in currently available form there is insufficient justification for permitting an appellant to engross what may prove to be a broad field...a patent is not a hunting license...[i]t is **not a reward for the search**, but compensation for its **successful conclusion**. [emphasis added]

These microarray of the instant application fails to have this substantial utility because the probes on the microarray, by their presence or absence, do not provide a real-world applicability to one ordinarily skilled in the art.

The probes (which make up the microarray) as disclosed, do not provide to one of ordinary skill in the art, what their presence or the absence would be useful for. For a probe to have a **substantial or real-world** utility, its presence or absence must relay to the ordinarily skilled artisan a real-world applicable information, such as detection/predisposition of certain conditions (i.e., cancer markers) (emphasis added). A statement indicating that the array of probes has substantial utility because it can, detect polymorphisms would not give an **immediately apparent**, or substantial utility as court has expressed because such apparent utility would not be found without conducting **further research** on each of the claimed polymorphisms (emphasis added). The claimed microarray lacks a substantial utility because the specification of the instant application fails to provide any guidance that the presence/absence of the claimed nucleic acids correlate to some disease, condition, or presence of harmful agents (i.e., bacteria), etc. The instant application simply relies on the fact that the probes have been patentable in the art and since the claimed microarray comprises probes, it must be patentable. Such reasoning is flawed because nucleic acid probes are not patented solely on their ability to hybridize to their complement. It is the information (a specific benefit, or an immediately applicable benefit) which is gleaned from the hybridization.

While it is true that a probe (which make up the array) would be found to have an immediately apparent utility, **if**, by its over-expression or under-expression, an artisan could derive a

useful information (such as diagnostic for conditions). However, the instant specification fails to disclose any of such benefit. The artisan using the microarray of the instant application would not know why the artisan should use the microarray of the claimed probes over other microarray comprising different probes that are isolated from plants, (i.e., maize). Without conducting further research, the artisan would not have any reason, such as an immediately apparent benefit, to use the claimed microarray comprising the recited SEQ ID Numbers.

At best, Applicants have provided a microarray comprising probes isolated plants, wherein, each probe of the microarray would require further research to find its substantial utility. Such would not be demonstrative of a substantial utility for the claimed subject matter.

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. See In re Fisher, 421 F.3d 1356, 76 USPQ2d 1225 (Fed. Cir. 2005). The Fisher court interpreted the above-discussed Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility." 421 F.3d at 1370, 76 USPQ2d at 1229. The Fisher court held that 101 requires a utility that is both substantial and specific. Id. At 1371, 76 USPQ2d at 1229. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some further date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that claimed invention has a significant and presently available benefit to the public." Id., 76 USPQ2d at 1230.

The Fisher court held that none of the uses asserted by the applicant in that case were either substantial or specific. The uses were not substantial because "all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter,

could possibly achieve, but none for which they have been used in the real world." Id. At 1373, 76 USPQ2d at 1231.

Accordingly, the claimed subject matter fails to satisfy the utility as required under 35 U.S.C. 101 for the above reasons.

Response to Arguments:

Applicants, on page 3 of the Response state that the Office has not provided any support for the assertion that the genes can be expressed only during a given condition or must be specific to a certain disease or agronomic trait to satisfy the utility requirement.

Applicants are advised that whether the mere isolation of expressed nucleic acid sequences (ESTs) in a collective form, absent a substantial utility, is the issue central to determining whether the claims meet the utility requirement.

This issue has already been addressed by the Board, the decision (herein, "Decision") of which was rendered on November 22, 2005, affirming the Office's position that the claimed nucleic acids had no substantial utility (see page 3 of Decision).

In addition, Applicants' arguments made in the Appeal to which Decision was rendered, clearly communicated that claims 8-10 stand or fell together (see page 6, Decision) with claim 11.

The Board rendered the decision affirming the lack of utility rejection of claim 11, explicitly stating that claims 8-10 fell together with the decision rendered for claim 11 (see page 17, top paragraph, Decision).

Applicants have since then amended claim 8 to add the limitation which only recites the intended use – "wherein said microarray is capable of analyzing biological samples for the presence of maize nucleic acid sequences."

This limitation, in no way, distinguishes the claims in which Board had already rendered their decision on. The claim is drawn to a product, the product of which is defined by its SEQ ID Numbers. The Board rendered its decision affirming the lack of utility of the claimed product based on the consideration of the claimed SEQ ID Numbers and the specification assertion of their possible uses.

Hence, Applicants' arguments drawn to claims 8-10 are rendered moot in view of Board's decision which already held that the claims lacked utility.

The rejection of claims 8-10 is maintained therefore.

Applicants' arguments will be addressed to the extent applicable to pending claims which were added with the filing of RCE, filed on January 23, 2006, namely, claims 12-27.

Applicants state that, "[a]s previously stated, the claimed microarrays contain nucleic acid sequences from maize corresponding to genes expressed during anthesis...as such, the claimed microarrays can be used, for example, for analyzing biological samples for the presence of maize nucleic acid sequences relating to genes expressed during anthesis or for high-throughput monitoring of gene expression of such genes without the need for ***further research to determine whether the sequences are expressed exclusively during anthesis***." (page 3, 2nd paragraph, Response).

This argument is not found persuasive.

While Applicants are stating that the microarray *can be used* to determine whether the sequences are expressed exclusively during anthesis, this fact is a clear evidence that the microarray as provided in the claims do not have substantial and specific utility.

While Applicants can state that the nucleic acids of the claimed microarray was expressed during anthesis, such statement can be made about any nuclei acids. All nucleic acids are expressed

at some point. While one of skilled in the art would recognize that a unique expression (e.g., overexpression, underexpression, or expressed at some point while absent during some point) of a particular nucleic acid for a particular phenotype, condition or state would have an immediately applicable utility, the microarray of the claimed invention does not disclose such knowledge.

Rather, one of skilled in the art would recognize that he/she would need to conduct further research, so as to identify, from the claimed microarray, whether any one of the nucleic acids are overexpressed, underexpressed, or expressed during anthesis while not in other conditions. This is a clear indication that Applicants have not arrived at a substantial utility.

In fact, Applicants' argument is equivalent to an assertion that any collection of nucleic acids, for example, which are expressed from a person inflicted with HIV, are useful. Clearly, to the contrary, one of skill in the art would ***not recognize*** that any of the nucleic acid would be immediately useful, but that they would need to conduct ***further research***, so as to identify nucleic acids which are substantially and specifically implicated with HIV.

To reiterate the court's decision in *Brenner v. Manson*, 148 USPQ 689 (1966), the court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. 101, which requires that an invention must have either an **immediately apparent** or fully disclosed "real world" utility (emphasis added). The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form there is insufficient justification for permitting an appellant to engross what may prove to be a broad field...a patent is not a hunting license...[i]t is **not a reward for the search**, but compensation for its **successful conclusion**. [emphasis added]

One of skill in the art would need to apply the claimed microarray in further research to arrive the successful conclusion for at least one nucleic acid comprised in the claimed microarray.

Tiling a bunch of expressed nucleic acid sequences on an array and asserting that such could be useful for research tool does not allow a skilled artisan to envision what the microarray would be useful for without conducting further research.

In *In re Fisher*, 421 F.3d 1356, 76 USPQ2d 1225 (Fed. Cir. 2005), the court held that 101 requires a utility that is both substantial and specific. Id. At 1371, 76 USPQ2d at 1229. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some further date after further research.

Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that claimed invention has a significant and presently available benefit to the public." Id., 76 USPQ2d at 1230.

What Applicants are asserting as substantial and specific utility is clearly based on what "it may be useful at some further date after further research," (Fisher).

Applicants state that the Office appears to focus on the utility of the individual nucleic acid sequences contained on the claimed microarray (page 3, bottom paragraph, Response).

Applicants state that claims must be considered as a whole in determining compliance with 101 and that it is inappropriate to dissect claims and consider some elements while ignoring others (page 4, top paragraph).

This argument is not found persuasive because claims are drawn to a microarray comprising at least 1000 nucleic acid molecules where at least 10% of the nucleic acid molecules are comprised

of different sequences and at least 250 nucleotide residues complementary to a molecule comprising a sequence selected from the group consisting of a plurality of SEQ ID Numbers.

The claims are drawn to a product. The product, as the claims recite, are defined by SEQ ID Numbers and the patentability is based on the SEQ ID Numbers. The Office is entirely correct in determining the patentability of the claims based on the SEQ ID Numbers recited in the claims.

Applicants state that they are not claiming recited nucleic acid sequences in abstract, but rather as a whole microarray that comprise various nucleic acid sequences selected from the recited Markush group, and thus, Applicants contend that the Office's arguments that the patentability of the claims is based on the utility of individual nucleic acid sequences alone is improper (page 4, 1st paragraph).

This argument is not found persuasive because Applicants are contending that a collection of elements which do not have substantial utility, when claimed as a collection, has substantial utility.

What Applicants are stating is that a nucleic acid was isolated from a sample, which has no disclosed immediately applicable utility, other than the fact that it is expressed in sample (thus has no utility), when coupled with another expressed nucleic acid which has no disclosed immediately applicable utility, result in an immediately applicable utility.

Clearly, this reasoning is illogical.

Applicants state that the Office has acknowledged that microarrays in general have a specific and substantial utility by way of their "utility for being able to analyze a plurality of nucleic acid samples simultaneously" (page 4, 2nd paragraph) referring to the Examiner's Answer dated May 23, 2003 at page 8 and Board Decision mailed November 22, 2005 at page 10.

Applicants based on this statement, argue that the claimed microarrays similarly have the ability to analyze a large number of nucleic acid molecules in a sample simultaneously, for example,

for the presence of maize nucleic acid sequences expressed during anthesis within the sample (page 4, 2nd paragraph, Response).

Applicants are mischaracterizing the statements made by the Office Action and the Board as the fact patterns from which the statement was made was out of context.

On page 8 of Examiner's Answer mailed May 23, 2003, the following was stated:

> **Appellants cite patent (U.S. 5,445,934) which claimed an array of oligonucleotides without specific sequences. Appellants confuse the patentability of a general microarray versus the microarray of the instant application. The '934 patent is drawn to a microarray comprising a plurality of oligonucleotides (not specific sequences) and patented by its utility for being able to analyze a plurality of nucleic acid samples simultaneously (including being able to analyze binding affinities). This is a practical and immediately apparent utility. However, the utility of the present microarray is directly dependent upon the nucleic acid molecules which the microarray comprises. Because the nucleic acid molecules which make up the claimed microarray require further experimentation to identify an immediately apparent utility, the microarray as a whole lacks utility that is substantial.**

The statement was made in response to Applicant's citation of U.S. Patent No. 5,445,934 which claimed an array of oligonucleotide ***without specific sequences***.

It was pointed out that the array of the '934 patent had utility in its concept of being able to analyze a plurality of nucleic acid samples simultaneously, but ***"the utility of the present microarray [was] directly dependent upon the nucleic acid molecules which the microarray comprises***."

Similarly, on page 10 of the Board's decision, the following was stated:

Accordingly, to the extent that appellants assert that microarrays in general may have utility as demonstrated by Pirrung and Fodor, we agree. To the extent that appellants assert that Pirrung and Fodor demonstrate that the specific microarray set forth in appellants' claim 11 is useful, we disagree. In our opinion, the utility of a microarray is dependent on the reagent, in this case the nucleic acid molecules, associated with the microarray. In this regard, appellants

The arguments are not found persuasive.

Applicants, on page 5, assert that they have met the bargain set forth in the Brenner v. Manson 383 U.S. 519, 534-35, 148 USPQ 689, 695 (1966), disclosing microarrays which, in their current form, provide at least one specific benefit to the public, use to analyze biological samples for the presence of maize nucleic acid sequences.

Examiner disagrees.

What Applicants have provided was microarrays, which in currently disclosed form, is useful for ***conducting further research*** so as to identify nucleic acid which might have an immediately applicable use.

This is precisely the conclusion made by Fisher 421 F.3d 1365, 76 USPQ 2d 1225 (Fed. Cir. 2005) (at page 13):

genes have no known functions. Fisher, nevertheless, claims that this fact is irrelevant because the seven asserted uses are not related to the functions of the underlying genes. We are not convinced by this contention. Essentially, the claimed ESTs act as no more than research intermediates that may help scientists to isolate the particular underlying protein-encoding genes and conduct further experimentation on those genes. The overall goal of such experimentation is presumably to understand the

Applicants cite various statements expressed by the court in *In re Fisher*, discussing that the court indicated that the specification disclose that an invention is useful to the public as disclosed in its current form; and that the specification also show that the claimed invention can be used to provide a well-defined and particular benefit. (page 5, bottom to page 6, 1st paragraph, Response).

It appears that Applicants have failed to discuss how the court in Fisher stated that not only the court agreed with the Office's holding of the lack of utility for the claimed EST, ***but also*** with "[s]everal academic institutions and biotechnology and pharmaceutical companies" (see page 8, Fisher).

The court explicitly state the below (page 9, Fisher):

We agree with both the government and the amici that none of Fisher's seven asserted uses meets the utility requirement of § 101. Section 101 provides: "Whoever

In addition, the "seven asserted uses" asserted by the Appellant of Fisher is as below:

The '643 application generally discloses that the five claimed ESTs may be used in a variety of ways, including: (1) serving as a molecular marker for mapping the entire maize genome, which consists of ten chromosomes that collectively encompass roughly 50,000 genes; (2) measuring the level of mRNA in a tissue sample via microarray technology to provide information about gene expression; (3) providing a source for primers for use in the polymerase chain reaction ("PCR") process to enable rapid and inexpensive duplication of specific genes; (4) identifying the presence or absence of a polymorphism; (5) isolating promoters via chromosome walking; (6) controlling protein expression; and (7) locating genetic molecules of other plants and organisms.

Clearly, the court in Fisher found none of the above-asserted uses met the utility requirement, the asserted uses of which are identical to the asserted uses Applicants are contending herein.

In fact, the court in Fisher goes stated that granting of a patent to Fisher in its disclosed form (ESTs), would amount to a "hunting license" which the court in Brenner v. Manson expressly prohibited that a patent be used for (page 19, Fisher):

Brenner, 383 U.S. at 535-36 (citations, quotation, and footnote omitted). Here, granting a patent to Fisher for its five claimed ESTs would amount to a hunting license because the claimed ESTs can be used only to gain further information about the underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of Fisher's research effort, but only tools to be used along the way in the search for a practical utility. Thus, while Fisher's claimed ESTs may add a noteworthy

As such, Applicants have not provided a substantial and specific utility for the claimed microarray, and the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 8-10 and 12-27 under 35 U.S.C. 112, first paragraph based on the reasoning that since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, made in the Office Action mailed on March 8, 2006 is maintained for the reasons of record.

Applicants' arguments presented in the Amendment received on June 7, 2006 have been fully considered but they are not found persuasive as the rejection of the claims for lacking patentable utility has been maintained as discussed above.

The rejection is maintained therefore.

The rejection of claims 8-10 and 12-27 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, made in the Office Action mailed on March 8, 2006 is maintained for the reasons of record.

Applicants' arguments presented in the Amendment received on June 7, 2006 have been fully considered but they are not found persuasive for the reasons set forth in the, "Response to Arguments" section.

The Rejection:

The specification discloses claimed SEQ ID Nos, which corresponds to the cDNA associated with plants (i.e., *Zea mays*). The claimed SEQ ID Numbers meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 8-10 and 12-27 recite nucleic acid comprising the claimed SEQ ID Numbers. Because it is not apparent from the specification that the claimed SEQ ID Numbers contain a full open reading frame, the claimed nucleic acids of SEQ ID Numbers read on cDNAs of full open reading frame. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of recited SEQ ID Numbers, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only the recited SEQ ID Numbers but not the full breadth of the claim (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Response to Arguments:

Applicants contend that they have provided the nucleotide sequences recited by the claims and have disclosed microarrays comprising such sequences, and have thus established possession of the claimed invention (page 9, 2nd paragraph, Response).

Applicants' statement is correct *in part.* Applicants do disclose a microarray comprising the nucleic acids of recited SEQ ID Numbers.

However, the full breadth of the claims not only embrace the above-discussed embodiment, but also microarray "comprising at least 250 nucleotides" that are complimentary to a collection of SEQ ID Numbers.

Hence, the full-breadth of the claims read on microarray comprising full-length gene which are complementary to SEQ ID Numbers, the genes of which comprising additional sequences in addition to the 250 complementary nucleotides.

The specification clearly demonstrates that the nucleic acid of the SEQ ID Numbers are ESTs, and no evidence is shown that they have identified the entire open-reading frame of from which these ESTs are derived from.

While Applicants' arguments stating that the specification describes, for example, vectors comprising the claimed nucleic acid molecules (page 9, 2nd paragraph, Response), Applicants are not claiming vectors comprising the nucleic acids of the recited SEQ ID Numbers.

Applicants' language of choice in the claims clearly intend to embrace microarray comprising nucleic acids comprising full open reading frame based on their partial disclosure of the nucleic acid therein.

Applicants state that they describe how to make the nucleotide sequences and libraries from which they [nucleic acids of the claims] were originally purified (page 10, 2nd paragraph, Response).

If Applicants are contending that by a generic disclosure of a method of making a nucleotide library serves as justification for written description for full open reading frame comprising the partial fragments of the disclosed SEQ ID Numbers, this type of argument had already been decided in Lilly.

In Lilly, the court, citing *Fiers v. Revel* (984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993), expressed that "[a]n adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish to plan for obtaining the claimed chemical invention."

In Lilly, the specification (U.S. Patent No. 4,652,525) disclosed an explicit example of producing cDNA from pancreas of rats (see column 15, line 39-40 and through column 17, line 36). The specification also gave guidance drawn to generating cDNA of human insulin (column 19, line 50 through column 20, line 14), wherein the specification **even disclosed the amino acid sequences** encoding human insulin A (column 19, lines 64-65) and the amino acid sequences encoding human insulin B (column 20, lines 5-10).

However, the court, deemed that claims drawn to cDNA encoding human insulin were not described. While one of skill in the art would have been able to derive every possible nucleic acid sequence encoding the insulin based on codon degeneracy (every possible nucleic acid sequence which must, undoubtedly include that which is of human), based on the disclosed amino acid sequence of human insulin, the court required the actual "DNA itself." (at 1405) and expressing that description cannot be established based on a "***mere statement that it is part of the invention and reference to a potential method for isolating it***."

This is precisely the situation here.

Applicants are claiming a microarray which clearly embraces full-length nucleic acids that comprise the fragments of nucleic acids of the recited SEQ ID Number, purely based on their contention that it is part of their invention and a potential method of isolating it.

Applicants also contend that one of skill in the art "has the **ability to make and use** the claimed microarrays based on the disclosure of the present specification, as well as envision a nucleic acid molecule that is complementary to any of the nucleic acid molecules of the claimed microarray." (page 10, 2nd paragraph, Response).

With regard to Applicants' statement regarding "make and use," this argument appears to be misplaced as the written description is not based on, "make and use" but rather the subject matter which was described in the specification reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (i.e., written description requirement).

With regard to Applicants' contention that one of skill in the art would be able to "envision a nucleic acid molecule that is complementary to any of the nucleic acid molecules of the claimed microarray," is not entirely accurate.

Applicants' appear to focus their arguments based on some of the embodiments which appear to justify their position and completely do not address the embodiments which they cannot justify.

For example, Applicants state that, "the addition of extra nucleotides or detectable labels to the sequences present on the claimed microarrays is readily envisioned by one of ordinary skill in the art" (page 10, 2nd paragraph, bottom, Response).

What Applicants clearly fail to demonstrate is the very embodiment which Office had already addressed in the previous Office Actions, which raised the question of whether one of skill

in the art would be able to recognize and envision that Applicants had possession of nucleic acid molecules of full-open reading frame, that "comprises" the fragments of nucleic acid molecules represented by the recited SEQ ID Numbers.

This embodiment is clearly intended to be covered by Applicants by the claim language they have employed – microarray comprising nucleic acid molecules of full-length open reading frame, which "comprises" the nucleic acid fragments represented by the recited SEQ ID Numbers.

To this respect, it is maintained that one of skill in the art simply cannot envision the extra sequences which possibly flank or are located at either end of the nucleic acid fragments represented by the recited SEQ ID Numbers.

The rejection is maintained therefore.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Young J. Kim
Primary Examiner
Art Unit 1637
8/15/2006

YJK